

ORIGINAL

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COMMENTS:

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Phone. 703.788.6570
Fax. 703.788.6545
www.sehsc.com
2201 Cooperative Way
Suite 600
Herndon, VA 20171

Via Certified Mail

October 3, 2012



TSCA Confidential Business Information Center (7407M)
EPA East – Room 6428
Attn: Section 8(e)
U.S. Environmental Protection Agency
Ariel Rios Building
1200 Pennsylvania Avenue, NW
Washington, DC 20460-0001

Re: TSCA Section 8(e) Notification: 2,4,6,8-tetramethyl-2,4,6,8-tetravinylcyclotetrasiloxane (CAS Number 2554-06-5)

Dear TSCA Section 8(e) Coordinator:

In accordance with the provisions of Section 8(e) of the Toxic Substances Control Act (TSCA), as interpreted in the TSCA Section 8(e) Policy Statement and Guidance, 68 Fed. Reg. 33129 (June 3, 2003) and other Agency guidance, the Silicones Environmental, Health and Safety Council (SEHSC)¹ submits, on behalf of its member companies, the following preliminary information concerning an *in vitro* mammalian chromosome aberration study with 2,4,6,8-tetramethyl-2,4,6,8-tetravinylcyclotetrasiloxane. Neither SEHSC, nor any member company, has made a determination at this time that any significant risk of injury to human health or the environment is presented by these findings.

Chemical Substance

2,4,6,8-tetramethyl-2,4,6,8-tetravinylcyclotetrasiloxane (CAS Number 2554-06-5)

Study

In vitro Mammalian Chromosome Aberration Test in Chinese Hamster V79 Cells with 2,4,6,8-tetramethyl-2,4,6,8-tetravinylcyclotetrasiloxane

Summary

The test article was evaluated for clastogenicity in Chinese Hamster V79 cells as outlined in the "O.E.C.D. Guidelines for Testing of Chemicals Guideline 473". Under the conditions of this study the test article was determined to be clastogenic.



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Details

Study Design:

The *in vitro* chromosomal aberration (CA) test is a mutagenicity test method for the detection of chromosomal aberration in cultured mammalian cells.

An asynchronous population of Chinese Hamster V79 cells in exponential growth was tested with and without metabolic activation. The cells were seeded into quadriperm dishes which contained microscopic slides (at least 2 chambers per dish and test group). Into each chamber, 1×10^4 – 5×10^4 cells were seeded with regard to preparation time. The medium was minimum essential medium supplemented with 10% FBS. In experiment I, cells were exposed for 4 hours to the following concentrations of test article (2.5, 5.0, and 10.0 $\mu\text{g/ml}$) with (S-9 mix in serum free media) and without activation. In experiment II, cells were exposed for 4 hours to the following concentrations of test article (0.4, 8.0, and 10.0 $\mu\text{g/ml}$) with (S-9 mix in serum free media) and 20 hours to the following concentrations of test article (0.04, 0.055, and 0.06 $\mu\text{g/ml}$) without activation. The solvent utilized was ethanol. Positive controls were conducted with the experiment and consisted of direct-acting (without activation) and indirect-acting (with activation) clastogens. Following exposure to the test substance, the cultures were washed twice with PBS and then the cells were cultured in complete medium for approximately 16 hours. The cell cultures were incubated at 37° C in humidified atmosphere with 5.0% CO₂ (95% air). Two and one half hours prior to cell preparation (fixation), cells were treated with Colcemid® to arrest cells in metaphase for analysis. After staining, at least 200 metaphases per concentration were evaluated for cytogenetic damage.

Results

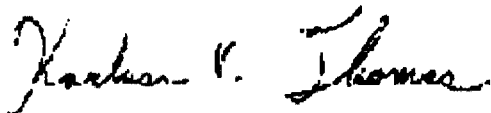
Chinese Hamster V79 cells following exposure to the test substance, with metabolic activation at concentrations of (0.4, 8.0, and 10.0 $\mu\text{g/mL}$), increases in aberration rates of 3.3%, 3.8%, and 6.5%, respectively were observed. Therefore under the conditions of this assay, the test article was considered to be clastogenic.

Actions

A copy of the final report "*In vitro* Mammalian Chromosome Aberration Test in Chinese Hamster V79 Cells with 2,4,6,8-tetramethyl-2,4,6,8-tetravinylcyclotetrasiloxane (CAS Number 2554-06-5)" will be provided when it is available.

If you have any questions concerning this submission, please contact me at (703) 788-6570 or at the address provided herein.

Sincerely,



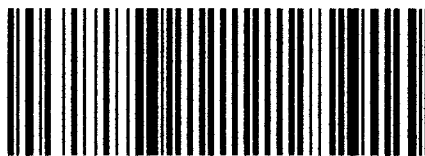
Karluss Thomas
Executive Director



**Silicones Environmental, Health & Safety
Council of North America**

2201 Cooperative Way
Suite 600
Herndon, VA 20171

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